DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED

HEALTH CARE FINANCING ADMINISTRATION OMB NO. 0938-0193

OFFICIAL FILE COPY

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: 02-06	2. STATE: Louisiana
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE June 10, 2002	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ■ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:	7. FEDERAL BUDGET IMPACT:
42 CFR 440.120	a. FFY 2002 ($8,141.21) b. FFY 2003 ($45,976.41)
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable):
Attachment 3.1-A, Item 12.a., Page 1 Page 2 Pages 3 & 4 Page 5 ** Page 6	Same (TN 98-11) Same (TN 94-06) Same (TN 95-26) None - New Page None - New Page

Louisiana (02-06)
Approved: 01/08/03
Effective: 06/10/02

10. SUBJECT OF AMENDMENT: **The purpose of this amendment is to provide for implementation of a prior authorization process with a preferred drug list (PDL) for certain designated drugs covered under the Medicaid Pharmacy Benefits Management Program.**

11. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT

☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

■ OTHER, AS SPECIFIED: **The Governor does not review state plan material.**

12. SIGNATURE OF STATE AGENCY OFFICIAL: David W. Hood	16. RETURN TO:
13. TYPED NAME: David W. Hood	State of Louisiana Department of Health and Hospitals 1201 Capitol Access Road PO Box 91030 Baton Rouge, LA 70821-9030
14. TITLE: Secretary	
15. DATE SUBMITTED: June 7, 2002	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: JUNE 10, 2002	18. DATE APPROVED: 8 JANUARY 2003

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 10 JUNE 2002	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME: ANDREW A. FREDRICKSON	22. TITLE: ASSOCIATE REGIONAL ADMINISTRATOR DIV OF MEDICAID & CHILDREN'S HEALTH

23. REMARKS:

** Pen + Ink Changes per State E-Mail 3-17-03 **

FORM HCFA-179 (07-92)

From: "ALLYSON LAMY" <ALAMY@dhh.state.la.us>
To: <mmarks@cms.hhs.gov>
Date: 3/17/03 1:33PM
Subject: TN 02-06

As per our conversation today, please make a pen and ink change to the form 179 on TN# 02-06 to add the following page to proposed pages:
--Attachment 3.1A, Item 12a, Page 6
This page replaces none as it is a new page.

Thanks for your assistance in this matter.

Allyson Lamy
Program Specialist
DHH/BHSF/Policy Development & Implementation
225-342-4294
alamy@dhh.state.la.us

CC: "Shirley GARLAND" <SGARLAND@dhh.state.la.us>

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

JAN 8 2003

David W. Hood
Secretary
Louisiana Department of Health and Hospitals
1201 Capitol Access Road
P.O. Box 629
Baton Rouge, LA 70821-0629

Dear Mr. Hood:

We have reviewed Louisiana's State Plan Amendment (SPA) 02-006, received in the Dallas Regional Office on June 10, 2002. The purpose of this amendment is to provide for implementation of a prior authorization process with a preferred drug list (PDL) for certain designated drugs covered under the Medicaid Pharmacy Benefits Management Program. We have reviewed your October 8, 2002 response to our September 5, 2002 request for additional information and your response is satisfactory. Therefore, we are pleased to inform you that your amendment is approved, effective June 10, 2002.

A copy of the form HCFA-179, as well as the pages approved for incorporation into the Louisiana state plan will be forwarded by the Dallas Regional Office. If you have any questions regarding this approval, please contact Marge Watchorn at 410-786-4361.

Sincerely,

Larry Reed
Co-Leader
Pharmacy Team

cc: Calvin Cline, ARA, Dallas Regional Office
Joe Reeder, Dallas Regional Office

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

CITATION		
42 CFR 440.120	Medical and Remedial Care and Services Item 12.a.	Prescribed drugs, and Prosthetic Devices; and Eyeglasses Prescribed by a Physician Skilled in Diseases of the Eye or by an Optometrist

Item 12.a. Prescribed drugs are limited as follows:

Vendor payments are made for prescribed medications and/or supplies listed below. The medications must be prescribed by a practitioner authorized to prescribe under state law. The National Drug Code (NDC) must be shown on each pharmaceutical claim form for reimbursement of prescription drugs subject to rebates from manufacturers as prescribed by mandatory federal law and regulations.

I. Program Coverage

A. **Covered Drugs.** Coverage of drugs shall be limited to specific drug products authorized for reimbursement by therapeutic category and listed by generic name, strength/unit, NDC, and brand name. Those drug products subject to mandatory coverage as a result of a rebate agreement with the federal government shall be covered until written notice is received from the Centers for Medicare and Medicaid Services (CMS) that coverage will be terminated. Providers will be given prior notice of any termination as required under federal regulations.

The list of covered drug products shall be maintained in the Services Manual of the Medicaid Program of Louisiana.

B. **Prior Authorization with Preferred Drug List (PDL).** Effective June 10, 2002, as authorized by LA R.S. 46:153.3 (B)(2)(a) and pursuant to 42 U.S.C. s1396r-8, a prior authorization process is established. This process utilizes a preferred drug list (PDL) for selected therapeutic classes. Drugs included on the PDL are automatically prior authorized. Drugs in

STATE Louisiana
DATE REC'D 6-10-02
DATE APPV'D 1-8-03
DATE EFF 6-10-02
HCFA 179 02-06
A

SUPERSEDES: TN- 98-11

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

these classes that are not included on the PDL shall require prescribers to obtain prior authorization.

Providers will be notified of the drugs selected for placement on the PDL by therapeutic classes prior to implementation of the prior authorization process and as additional drugs are subsequently added to the list. Lists of covered drug products, including those that require prior authorization, will be maintained in either the Prescription Drug Services Manual, other designated service provider manuals, on the Louisiana Medicaid web site, or provider notices.

The Prior Authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four (24) hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two (72) hour supply of medication as mandated by LA R.S. 46:153.3 (B)(2)(a) and pursuant to 42 U.S.C.s1396r-8.

The Pharmaceutical and Therapeutics Committee will make recommendations to the Department regarding drugs to be subject to the prior authorization. The composition of and appointment to the Pharmaceutical and Therapeutics Committee complies with LA R.S. 46:153.3(D) and 42 U.S.C.s1396r-8. The Committee is appointed by the Governor and approved by the Senate.

The Pharmaceutical and Therapeutics Committee was established by State law in 2001 to advise the Department of Health and Hospitals (DHH) regarding the prescription drug program. The Committee reviews monographs on selected therapeutic drug classes or individual drugs and makes recommendations to the DHH for inclusion either on the Preferred Drug List (PDL) or on the Non-preferred Drug List (NPDL).

STATE Louisiana
DATE RECD 6-10-02
DATE APPVD 1-8-03
DATE EFF 6-10-02
HCFA 179 02-06

A

SUPERSEDES: TN- 94-06

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

Drugs on the PDL do not require prior authorization, and drugs on the NPDL require authorization. The monographs include clinical data, utilization data, therapeutic information relative to populations (i.e. elderly and pediatric use), multiple source availability (generic and innovator products) and relative cost information (state and federal rebate information is confidential). The Medicaid Pharmacy Benefits Management Program staff compiles the Committee's recommendations along with staff comments and/or additional information as necessary and submits them to the DHH Secretary for consideration.

C. **Drugs Excluded from Coverage.** The Medicaid program, based on recommendations by the State's Medicaid Pharmaceutical and Therapeutics Committee, may include or exclude drug product coverage for those drugs and/or therapeutic categories subject to restriction under Section 1927(d)(2) of the Social Security Act subsequent to provider notification.

Exclusions include:

1. Experimental Drugs
2. Anorexics
3. Cough and cold preparations
4. Cosmetic Drugs
5. Compounded prescriptions (mixtures of two or more ingredients; the individual drugs will continue to be reimbursed)
6. Medications which are included in the reimbursement to a facility, i.e. hospitals, skilled nursing facility for recipients receiving benefits under Part A of Title XVIII, mental hospitals, or some other nursing facilities
7. Non-legend drugs with some exceptions
8. Fertility drugs when used for fertility treatment
9. Vaccines covered in other programs

SUPERSEDES: TN: 95-26

STATE	Louisiana
DATE REC'D	6-10-02
DATE APP'VD	1-8-03
DATE EFF	6-10-02
HCFA 179	02-06
	A

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

10. DESI Drugs (see D. below)

D. **DESI Drugs.** Those drugs subject to a Notice of Opportunity for Hearing (NOOH), as prescribed by Section 1927 (k)(2)(A) of the Social Security Act, for which the Food and Drug Administration has proposed to withdraw from the market because they are "less than effective" or "identical, related, or similar drugs" which are identified as DESI ineffective drugs shall be excluded from coverage.

E. **Drugs for Erectile Dysfunction.** The number of units of prescription drugs for the treatment of erectile dysfunction reimbursable by Medicaid is limited to six (6) units per month per patient. Units include tablets, injectable, intraurethal pellets and any other dosage form which may become available.

II. Supplemental Drug Rebates

A. As authorized by LA R.S. 46:153.3 (B)(2)(a) the State Supplemental Drug Rebate program is effective April 1, 2002.

B. The state negotiates supplemental rebates from manufacturers that are in addition to those mandated by Title XIX of the Social Security Act.

C. The Department is in compliance with Section 1927 of the Social Security Act. Based on the requirements for Section 1927, the state has the following policies for drug rebate agreements:

1. The drug file permits coverage of participating manufacturers' drugs.
2. The program is in compliance with reporting for state utilization information and restrictions to coverage.

STATE Louisiana	A
DATE REC'D 6-10-02	
DATE APP'VD 1-8-03	
DATE EFF 6-10-02	
HCFA 179 02-06	

SUPERSEDES TN 95-26

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

3. Rebate agreements between the state and a drug manufacturer that are separate from the drug rebate agreements of Section 1927 are approved by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any state supplemental rebates collected.
4. Manufacturers are allowed to audit utilization data.
5. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
6. The Department will utilize the same processes to resolve State Supplemental rebate issues as it uses to resolve federal rebate disputes and as outlined in CMS' *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program.*

D. The Department is also in compliance with R.S. 44:4 as amended by Act 124 of The First Extraordinary Session of the 2002 Legislature relative to the confidentiality of supplemental rebate information contained in the records of the Department and its agents.

E. A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on April 8, 2002 and entitled "Supplemental Rebate Agreement" was previously authorized by CMS on April 25, 2002.

STATE Louisiana	A
DATE REC'D 6-10-02	
DATE APP'D 1-8-03	
DATE EFF 6-10-02	
HCFA 179 02-06	

SUPERSEDES: NONE - NEW PAGE

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED

LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

III. Limits on Allowable Cost

Provider reimbursement limits on cost as established under Attachment 4.19-B must be followed. These limits neither supercede or contravene State anti-substitution laws. Pharmacists shall not be authorized or required to dispense drugs in violation of State Law.

IV. Recipient Co-Payments

Effective for dates of service July 13, 1995 and after, the Department of Health and Hospitals, Bureau of Health Services Financing, imposes a co-payment requirement in the Pharmacy Program as reflected on Attachment 4.18-A, Page 1.

In accordance with Federal regulations the following provisions apply: 1) the provider may not deny services to any eligible individual on account of the individual's inability to pay the co-payment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the co-payment. Providers shall not waive the recipient co-payment liability. Departmental monitoring and auditing will be conducted to determine provider compliance. Violators of this policy will be subject to a penalty such as suspension from the Medicaid program.

STATE Louisiana
DATE RECD 6-10-02
DATE APPVD 1-8-03
DATE EFF 6-10-02
HCFA 179 02-06

A

SUPERSEDES: NONE NEW PAGE